

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

Claims 1-37 (cancelled)

38. (Currently Amended): A method of treating migraines, cluster headaches, muscle sprains, muscle spasms, spasticity, tension headaches and tension related migraines with a topical formulation comprising applying a unit dose of a therapeutically effective amount of an active agent(s) **comprising tizanidine or a pharmaceutically acceptable salt thereof** incorporated into an immediate release pharmaceutically acceptable excipient onto the skin of a human patient **experiencing a condition selected from the group consisting of migraine, cluster headache, muscle sprain, muscle spasm, spasticity, tension headache and tension related migraine** at the posterior cervical area in close proximity to the brain stem, ~~the unit dose comprising an active agent(s) being selected from the group consisting of:~~

- i) an ergot alkaloid;
- ii) a skeletal muscle relaxant; or
- iii) a combination of an ergot alkaloid and a skeletal muscle relaxant;

such that the unit dose **provides** providing a therapeutic effect within about 2 hours after topical administration to the human patient.

39. (Original): The method of claim 38, wherein the formulation further comprises a therapeutically effective amount of a serotonin agonist.

Claims 40-43 (Canceled)

44. (Original): The method of claim 43, wherein the spasticity results from complication suffered in a stroke.

45. (Currently Amended) The method of claim 38, further comprising incorporating the active **agent** agents into an aqueous based formulation.

46. (Previously Presented) The method of claim 38, further comprising incorporating a permeation enhancer into the topical formulation.

47. (Previously Presented) The method of claim 38, further comprising preparing the topical formulation in a form selected from the group consisting of a liquid, a semisolid, a solid and mixtures thereof.

48. (Previously Presented) The method of claim 47, further comprising preparing the unit dose of the liquid in the form of drops, tinctures, sprays, suspensions, lotions, emulsions, dispersions or mixtures thereof.

49. (Previously Presented) The method of claim 47, further comprising preparing the semisolid in the form of an ointment, cream, foam, paste, gel or mixtures thereof.

50. (Previously Presented) The method of claim 47, further comprising preparing the solid is in the form of a powder, granulates, pellets, microcapsules or mixtures thereof.

51. (Previously Presented) The method of claim 38, further comprising incorporating a therapeutic amount of active agent(s) into the unit dose such that the active agent(s) would provide a subtherapeutic plasma level if orally administered, but are therapeutically effective when administered topically at the posterior cervical area.

52. (Currently Amended) The method of claim 38, wherein the unit dose provides pain relief in at least 70%, preferably at least 80%, and most preferably at least 90% of a population of patients.

53. (Currently Amended) The method of claim 38, wherein the unit dose further comprises a therapeutically effective amount of an ergot alkaloid is selected from the group consisting of bromocriptine, ergocristine, ergocristinine, ergotamine, ergotaminine, ergocryptine, ergocryptinine, ergocornine, ergocorninine, ergosine, ergosinine, ergonovine, ergometrinine, dihydroergotamine, lisuride, d-lysergic acid, d-isolysergic acid, lysergol, lergotrile, metergoline, methysergide, methylergonovine, pharmaceutically acceptable salts thereof, ~~active metabolites thereof, prodrugs thereof~~ and mixtures thereof.

54. (Currently Amended) The method of claim ~~53~~ 39, wherein the ergot alkaloid is selected from the group consisting of dihydroergotamine base, dihydroergotamine mesylate, and mixtures thereof.

55. (Previously Presented) The method of claim 53, wherein the therapeutically effective amount of ergot alkaloid ranges from about 0.1 mg to about 10 mg, preferably from about 0.5mg to 6mg.

56. (Canceled)

57. (Previously Presented) The method of claim 38, wherein the muscle relaxant is tizanidine hydrochloride.

58. (Currently Amended) The method of claim 57, wherein the unit dose comprises from about 0.2mg ~~0.4 mg~~ to about 8 mg, ~~preferably from about 0.2 mg to about 4 mg~~ of tizanidine hydrochloride.

59. (Canceled)

Amdt. dated December 10, 2010

In response to Office Action dated June 11, 2010

60. (Currently Amended) The method of claim 38 39, wherein the serotonin agonist is selected from the group consisting of sumatriptan, naratriptan, eletriptan, rizatriptan, zolmitriptan, almotriptan, frovatriptan, pharmaceutically acceptable salts thereof, ~~active metabolites thereof, prodrugs thereof~~ and mixtures thereof.

61. (Previously Presented) The method of claim 60, wherein the serotonin agonist is sumatriptan.

62. (Previously Presented): The method of claim 61, wherein the unit dose comprises from about 0.5 mg to about 200 mg sumatriptan.

63. (Previously Presented) The method of claim 62, wherein the unit dose comprises from about 5 mg to 50 mg sumatriptan.

64. (Previously Presented) The method of claim 38, further comprising incorporating one or more additional active agents into the topical formulation.

65. (Previously Presented) The method of claim 38, further comprising incorporating one or more ingredients into the topical formulation selected from the group consisting of ethoxydiglycol, water, glycerine, C12-15alkyl benzoate, glycetyl stearate, dimethicone, cetearyl alcohol, cetearyl glucoside, polyacrylamide, cetyl alcohol, magnesium aluminum silicate, xanthan gum, aloe vera (aloe barbadensis), tocopheryl acetate (vitamin E acetate), prunus amygdalus amara (bitter almond) kernel oil, vitis vinifera (grape) seed extract, triticum vulgare (wheat) germ oil, retinyl palmitate (vitamin A palmitate), ascorbyl palmitate (vitamin C palmitate), pro-lipo multi-emulsion liposomal system, tetrasodium EDTA, phenoxyethanol, and sodium hydroxymethylglycinate.

66-67. (Canceled)

68. (New) The method of claim 57, wherein the unit dose comprises from about 0.4 mg to 8 mg, preferably from about 0.2 mg to about 4 mg of tizanidine hydrochloride.

69. (New) A method of treating migraines, cluster headaches, muscle sprains, muscle spasms, spasticity, tension headaches and tension related migraines with a topical formulation comprising applying a unit dose of a therapeutically effective amount of tizanidine or a pharmaceutically acceptable salt thereof and a therapeutically effective amount of sumatriptan or pharmaceutically acceptable salts thereof, incorporated into an immediate release pharmaceutically acceptable carrier, onto the skin of a human patient experiencing a condition selected from the group consisting of migraine, cluster headache, muscle sprain, muscle spasm, spasticity, tension headache and tension related migraine, at the posterior cervical area in close proximity to the brain stem of the human patient, such that the unit dose provides a therapeutic effect within about 2 hours after topical administration to the human patient.

70. (New) The method of claim 69, wherein the unit dose comprises from about 0.2mg to 8 mg of tizanidine hydrochloride and from about 0.5 mg to about 200 mg sumatriptan succinate.

71. (New) The method of claim 69, wherein the unit dose comprises from about 0.4 mg to 4 mg of tizanidine hydrochloride and from about 5 mg to 50 mg sumatriptan succinate.

72. (New) The method of claim 69, further comprising incorporating the tizanidine and the sumatriptan into an aqueous based carrier.

73. (New) The method of claim 38, wherein the unit dose provides a therapeutic effect within about 5 to about 30 minutes after application of the unit dose.

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74. (New) The method of claim 38, further comprising applying an additional unit dose onto the skin of the human patient at the posterior cervical area from about 15 minutes to about 3 hours after the first application of the unit dose.